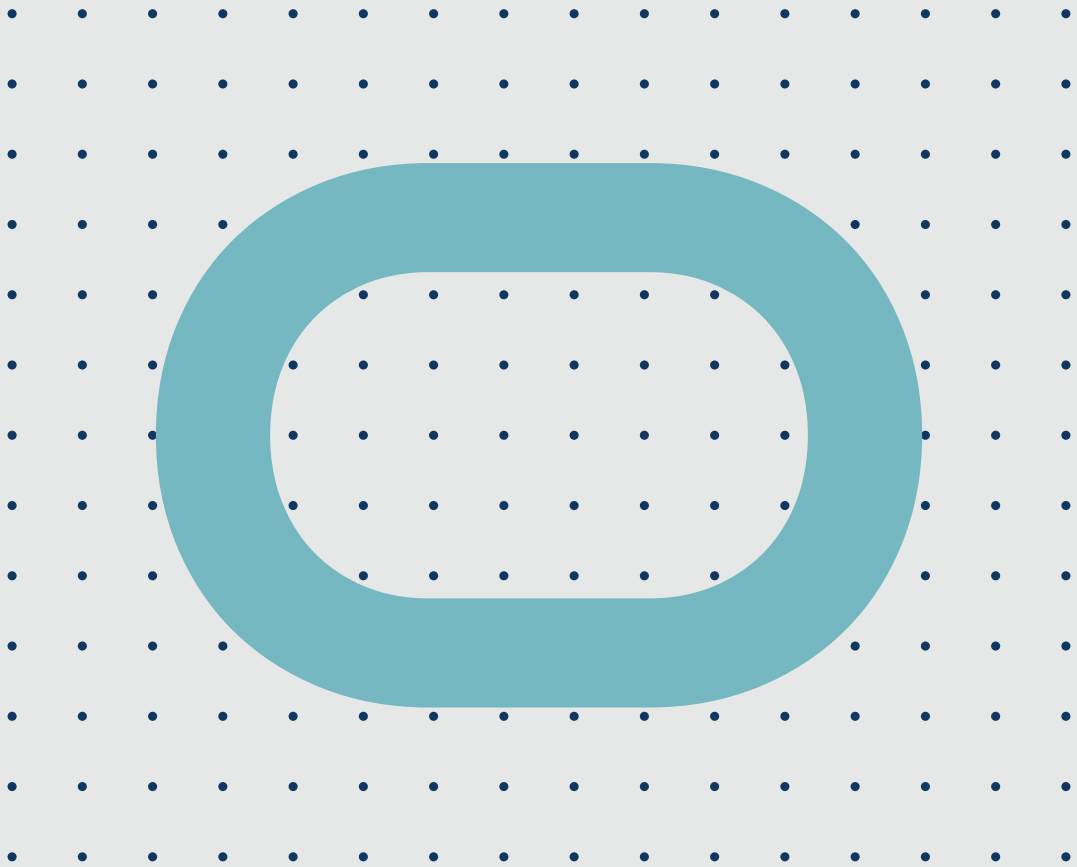


FULL CIRCLE IN LYOPHILISATION

By the laboratory's
side from formulation
to manufacturing.

comser | FREEZE-DRY SOLUTIONS

EXPERTS IN LYOPHILISATION

We help industrialise your lyophilised product from the formulation stage of the active ingredient to the routine manufacturing of the final product.

› BIOLOGICS
› INJECTABLES
› ATMPS

Lyophilisation is a key technology used for drug stabilisation in the pharmaceutical industry, a booming sector in recent years due to the development of new biopharmaceuticals that require reaching molecular stability through a controlled process.

BENEFITS OF LYOPHILISATION:

STABILISATION of product over time

Removal of the COLD CHAIN in transportation

Storage at ROOM TEMPERATURE

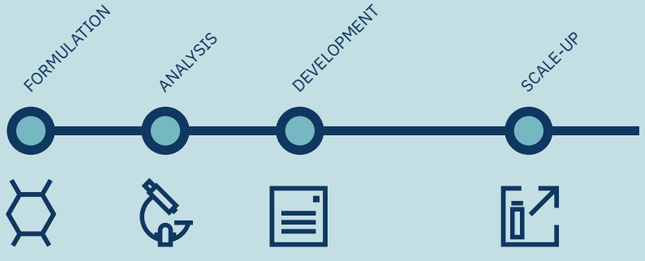
Increase of the SHELF LIFE of the product

COMSER arises as an international technical partner ready to offer simple solutions to the complex challenges posed by the lyophilisation process:

› More than 20 years' experience.
› R&D laboratory specialised in lyophilisation.
› Knowledge of the regulatory environment.
› Support in all the stages of the development of a lyophilised product.

COMSER ensures the quality and stability of the lyophilised product through a correct formulation and an optimised lyophilisation process.

WE HELP REDUCE THE TIME TO MARKET



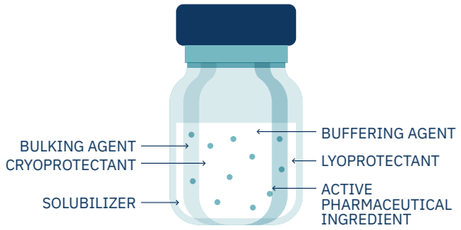
BY THE LABORATORY'S SIDE FROM FORMULATION TO MANUFACTURING.

comser

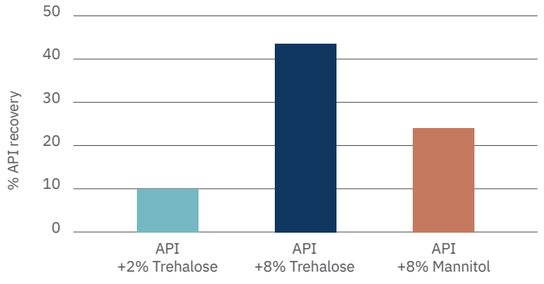
Design and improvement of the product's formulation

In lyophilisation, a correct design of the product's formula is essential to accomplish:

› Molecular **stability** of the active ingredient.
› Maintain the activity of the active ingredient.
› **Reduce** the generation of impurities.
› Minimise the number of **rejections** per batch.
› Build a molecular structure that can resist sublimation and drying.
› Increase **collapse** temperature to obtain shorter cycle times.



API RECOVERY



R&D LABORATORY

COMSER brings the necessary experience in lyophilisation to conduct a correct formulation of the product while maintaining the activity of the active ingredient:

› Small molecules, macromolecules, proteins
› Study of the nature of the active ingredient
› Functionality of the final product
› Route of administration
› Interaction of the excipients between themselves and with the active ingredient

FREQUENT PROBLEMS

WE HELP LABORATORIES IN THE IMPROVEMENT OF THEIR FORMULATIONS

Collapse, generation of impurities, decrease in the activity of the API, aggregations, pH changes... these are common problems that arise during an inappropriate lyophilisation cycle because of a potentially improvable formulation design.

The study of the nature of the active ingredient is the basis for providing the appropriate protection to ensure a correct lyophilised product.

Thermal characterisation of the product

Knowledge of the thermodynamic behaviour of the chosen formulas to be lyophilised is essential to identify the product's **critical temperatures**. **COMSER** has the technological tools and expertise needed to conduct the design of the freeze-drying process based on a **rational method**, with the time saving it entails.

CUTTING-EDGE TECHNOLOGY

_ FREEZE DRYING MICROSCOPY (FDM)

› Collapse temperature (T_c)
› Fusion temperature (T_f)
› Primary drying phase

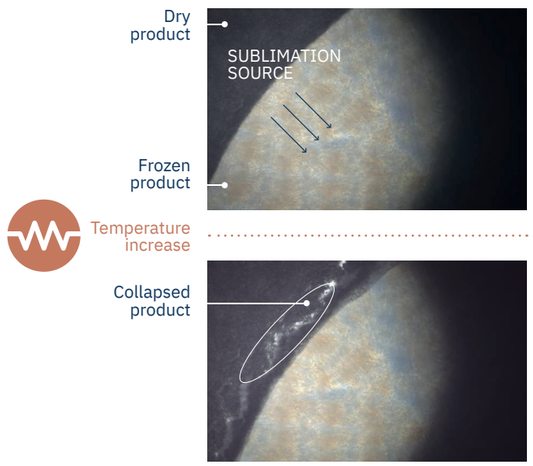
_ DIFFERENTIAL SCANNING CALORIMETRY (DSC)

› Glass transition temperature (T_g')
› Eutectic temperature (T_{eu})
› Freezing phase

LABORATORY CAPACITIES

PROCESS Know-how | Technological TOOLS

IDENTIFICATION of critical temperatures | Cycle DESIGN



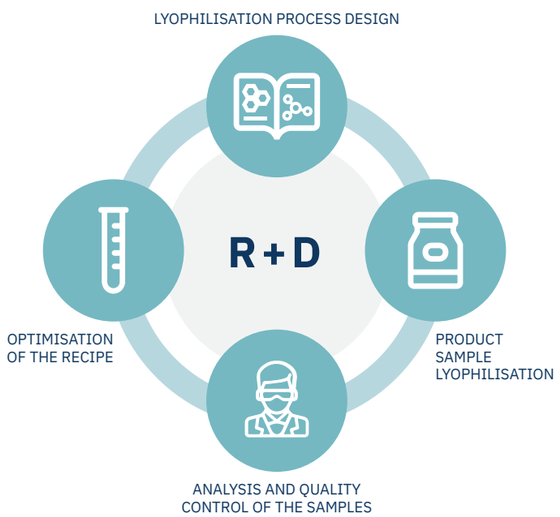
Design and optimization of the lyophilisation process

COMSER's goal is to obtain a product that complies with **the market's requirements and standards** through a lyophilisation cycle that is both easily scalable and as short as possible.

To achieve this, **COMSER** has the equipment, facilities, technological tools, and the expertise to carry out the design and optimisation of the lyophilisation process, looking for the product to meet predefined critical quality attributes, such as:

› **Integrity** of the lyophilisation cake
› Colour **uniformity**
› Residual moisture
› Reconstitution time
› **Sterility**
› API **recovery/activity**
› Impurity level

CYCLE TO EXCELLENCE



BENEFITS OF AN OPTIMISED PROCESS

COMSER's methodology and knowledge is crucial to optimising existing lyophilisation recipes. The optimisation of the process is key to increasing the efficiency of a drug.

REAL DATA. NEFTIS' SUCCESS STORY

PRODUCTIVITY BENEFITS

TIME REDUCTION OF THE CYCLE
-22,6%
(-21,5h)

THROUGHPUT INCREASE
900 vials/cycle at
1.700

PROFIT INCREASE

QUALITATIVE BENEFITS

HIGHER HOMOGENEITY
RMC: 1,2% - 5,3%
0,8%-1,4%

DEFECTS
-47%
rejects / batch

QUALITY INCREASE

Development and process scale-up in a clean room

DEVELOPMENT PHASE

COMSER has a development freeze-dryer that allows the company to obtain the first design results of the process and adjust the necessary parameters based on the analysis of the thermal characterisation of the product.

PRE SCALE-UP PHASE

Once the parameters are defined in the previous phase, **COMSER** has two pilot devices to test the scalability of the designed recipe.

COMSER FREEZE-DRYERS

BULK pilot freeze-dryer | CLEAN ROOM pilot freeze-dryer

COMSER is one of the few companies that has a clean room to carry out a clean process simulating grade A / ISO 5 conditions, **precisely reproducing future manufacturing conditions**.

This fact significantly reduces the process' transfer time at an industrial level, because it minimizes the number of external factors at the time of scaling up.

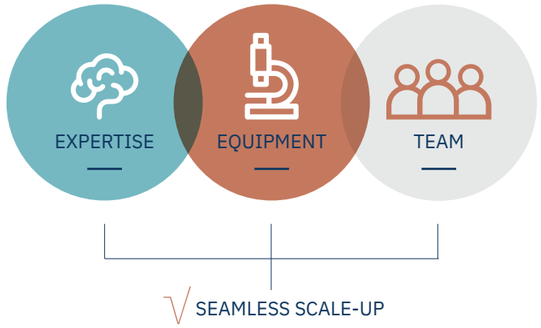
THE CLEAN ROOM ALLOWS US TO PRECISELY REPRODUCE FUTURE MANUFACTURING CONDITIONS

REQUEST A VIRTUAL VISIT TO OUR CLEAN ROOM WITH SMART CLEAN ROOM TECHNOLOGY

Transfer of the final lyophilisation process to the industrial plant

The key to a good scale-up is in-depth knowledge of the developed product, as well as the capabilities and performance of the industrial freeze-dryer.

The method used by **COMSER** ensures the product will be seamlessly scaled-up at the site, as the customer is assisted in the transfer of the optimized and pre-scaled recipe to their facilities.



COMSER successfully transfers the lyophilisation cycle defining each step's time at an industrial scale. Readjusting the parameters depending on the capabilities of the freeze-drying equipment in the industrial plant.

EQUIPMENT QUALIFICATION AND PROCESS VALIDATION

COMSER offers the possibility of qualifying equipment and validating productive proceses to he biopharmaceutical industry.

TRAINING

For professionals in the sector:

1. **In house** training
2. **Hybrid workshops** with both theory and practice
3. **Online and remote** training. Tailored content:

- Lyophilisation process and phases
- Cycle development and optimisation
- Parts, operation, and qualification of a freeze-dryer
- Freeze-dryer maintenance

DISTRIBUTION

Wireless sensors to measure the product temperature.

tempris® sensor technology

comser

- HIGH VALUE SERVICES -

FREEZE-DRY SOLUTIONS | HIGH VALUE TRAINING | GMP QUALIFICATION & VALIDATION | GMP AUDITS

Doctor Torras i Bages, 100 · 08223 Terrassa (BCN)
T (+34) 93 707 10 97 · info@comserpharma.com
WWW.COMSERPHARMA.COM